Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
P686 CON2	

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Signature _____

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Application Number	Filed
10/727,534	12/05/2003
First Named Inventor	
Eric P. Berg	
Art Unit	**Examiner**
3774	Ganesan, Suba

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 26,289
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Alan M. Krubiner
Typed or printed name

(707) 543-5420
Telephone number

June 26, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/727,534	Confirmation No.:	7333
Applicant	:	BERG, Eric P.		
Filed	:	December 5, 2003		
TC/A.U.	:	3774		
Examiner	:	Ganesan, Suba		
Docket No.	:	P686 CON2		
Customer No.	:	28390		
Title	:	Medical Device for Delivering a Therapeutic Substance and Method Therefor		

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Alexandria, VA 22313-1450

ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

ARGUMENTS ACCOMPANYING
PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

Claims 1-24 are pending in the application, with claim 1 being the sole independent claim. Claims 3, 6-8, 11, and 12 are withdrawn from consideration as being drawn to a nonelected species pending allowance of generic claim 1.

The Appellant appeals the rejection of Claims 1, 2, 4, 5, 9, 10 and 13-24 in the above-captioned application. These claims, as they appear in the Listing of Claims on pages 2-4 of the Reply filed December 28, 2007, were rejected in the Final Office Action dated April 2, 2008.

The following Arguments, beginning on page two (2), accompany the attached Pre-Appeal Brief Request for Review. No Amendments are being filed with these Arguments.

ARGUMENTS

35 U.S.C. §103 Rejections – Sahatjian and Miller et al.

Claims 1, 2, 4, 5, 9, 10, 13, 15, 16, 18-20, 22 and 23 stand rejected under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,304,121 to Sahatjian in view of U.S. Patent No. 5,760,200 to Miller et al. *See* Final Office Action dated April 2, 2008, pp. 3-4. Appellant traverses this rejection because the Examiner has failed to make a prima facie case of obviousness as Sahatjian alone or in combination with Miller et al. fail to teach a drug-eluting stent having "a porous material … with a plurality of particles of a water-insoluble salt of a therapeutic material dispersed throughout said porous material," as recited in independent claim 1.

The Examiner states that Sahatjian discloses the use of heparin salt as a therapeutic salt but does not "*specifically* disclose the heparin salt being water insoluble." *See* Final Office Action dated April 2, 2008, p. 4. In fact, Sahatjian only discloses use of heparin salt ***solutions*** for use in coatings thereof to provide rapid release of the therapeutic substance upon stent expansion. *See* Reply filed December 28, 2007, pp. 6-7 and Amendment filed July 16, 2007, p. 5.

The Examiner states that Miller et al. teaches the use of a "water insoluble polyanionic polysaccharide … which includes heparin … as a water insoluble composition in the form of a gel or film." *See* Final Office Action dated April 2, 2008, p. 4. This is an accurate statement of the teaching of Miller et al. Notably, the water insoluble composition of Miller et al. is a water insoluble film, foam, gel or other form suitable for application by syringe for use as an ***adhesion prevention composition*** after surgery to prevent post-operative adhesion between body tissues. *See* Reply filed December 28, 2007, p. 6. The water-insoluble property of the composition allows the composition to **prevent tissue contact** for a long enough period so that when the composition finally disperses and the tissues do come into contact, the tissues no longer have a tendency to adhere. *See*, Miller *et al.* col. 1, lines 33-42; col. 3, lines 63-66; col. 4, lines 45-49; and col. 15, lines 40-47. Miller et al. mentions a pharmaceutically active substance may be dispersed as a drug delivery system throughout the water-insoluble composition, but does not teach or suggest making ***the pharmaceutically active substance*** water-insoluble. *See*, Miller et al., col. 3, line 63 - col. 4, line 4. Thus, neither Sahatjian nor Miller et al. teaches or suggests "a

plurality of particles of a water-insoluble salt of a therapeutic material dispersed throughout [a] porous material" as recited in claim 1.

The Examiner states it would have been obvious "to modify heparin salt of Sahatjian with a water insoluble heparin composition as taught by Miller for the purpose of providing a substrate that is washable in water before use." *See* Final Office Action dated April 2, 2008, p. 4. Appellant contends that the Examiner's modification of the hydrogel polymer coated stent of Sahatjian to have a water-insoluble therapeutic material would not be obvious to one of skill in the art in view of Miller et al. for at least the following reasons.

1) There is no motivation to combine the references because the Examiner's suggested modification of Sahatjian would either change the principle of operation of Sahatjian or render it unfit for its intended purpose, as a water-insoluble salt of a therapeutic material would not provide ***a drug solution*** for rapid release of a desired dosage upon compression of the balloon coating. *See* Reply filed December 28, 2007, pp. 6-7; MPEP §2143.01. In response to this argument the Examiner stated that "attorney arguments cannot take the place of evidence" and that an affidavit would be needed to support "inoperability of the prior art" under MPEP 716.01. *See* Final Office Action dated April 2, 2008, p. 2, item 2. The Examiner is mistaken in requiring an affidavit from Appellant to support the aforementioned argument, as Appellant is not alleging the "inoperability" of the device of Sahatjian. Instead, Appellant is arguing that the Examiner's proposed modification of Sahatjian would render a coated device thereof unfit for its intended purpose (as a water-insoluble therapeutic material would not go into solution for rapid release) or change the principle of operation (as a water-insoluble therapeutic material would need to be distributed other than in solution as taught by Sahatjian). As such, Appellant asserts that the Examiner's proposed modification of Sahatjian would not be obvious to one of skill in the art.

2) The Examiner's articulated rationale that one of skill in the art would modify Sahatjian in view of Miller et al., *i.e.*, to realize the purported benefit of washability, is unreasonable and would not provide motivation to one of skill in the art to use a water-insoluble salt for a therapeutic solution according to Sahatjian. *See* Reply filed December 28, 2007, p. 6. Essentially, the Examiner reasoning ignores the medical device of Sahatjian includes the solution of a therapeutic material being trapped within a swellable hydrogel polymer coating. One of ordinary skill in the art would not find it desirable to "wash" a hydrogel polymer coated device of Sahatjian because this would cause the hydrogel coating to swell prior to insertion to a treatment site and likely lead to premature release of the therapeutic solution held therein. *See*

Sahatjian, Abstract. As such, Appellant contends that one of skill in the art would not be motivated to make a salt for use in a therapeutic solution of Sahatjian water-insoluble to achieve a "washable" medical device.

Appellant notes that in addressing the Examiner's "washability" rationale in the Reply filed December 28, 2007 that Appellant's remarks concerned the questionable benefit of having a washable drug eluting stent. Appellant incorporates these remarks herein and additionally notes that the Examiner's response to these arguments was that "it is desirable to wash a stent during manufacture and before sterilization." *See*, Final Office Action dated April 2, 2008, p. 2, item 1. While this may be so, it does not provide any further insight into why once a coating of a therapeutic material is applied to a stent that it would than be desirable to wash the drug eluting stent? It is Appellant's position that washing a drug-eluting stent according to claim 1 of the present application would likely result in a loss of particles of a water-insoluble salt of a therapeutic material dispersed throughout the porous material covering the stent, such as by the flushing/rinsing action of "washing," and therefore would not be a reason for making the therapeutic material within the pores water-insoluble.

In addition, the Examiner's remark regarding "unreacted" substances being removed as suggested by Miller et al. begs the question as to what substances are "unreacted" in a drug-eluting stent. Washing a gel or foam composition according to Miller *et al.* in water to remove unreacted substances is relevant because unreacted polyanionic polysaccharides would not be water insoluble, which would leave them free to react/dissolve *in vivo*. *See* Miller *et al.* col. 2, lines 51-56; col. 3, lines 42-58. The Examiner lacks basis for his statement that "unreacted" substances are present in a drug loaded stent that would lead one of skill in the art to find a benefit in making a salt of a therapeutic material water-insoluble according to claim 1.

For at least the foregoing reasons, the Examiner has failed to show proper motivation for making a modification of the device of Sahatjian in view of Miller et al. and therefore the combination of Sahatjian and Miller et al. fails to teach or suggest all the limitations of claim 1. Therefore, the Examiner has failed to make a *prima facie* case of obviousness against claim 1. See MPEP 2143.03. Claims 2, 4, 5, 9, 10, 13, 15, 16, 18-20, 22 and 23 depend from and add further features to independent claim 1 and are patentable for that reason alone.

35 U.S.C. §103 Rejections – Sahatjian, Miller et al., Hunter et al. and/or Tang et al.

Claims 14, 17 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sahatjian and Miller *et al.* as applied to claim 1 above and further in view of U.S. Patent No. 5,716,981 to Hunter *et al.* *See*, Final Office Action dated April 2, 2008, pp. 4-5. Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sahatjian and Miller *et al.* as applied to claim 1 above and further in view of U.S. Patent No. 5,304,121 to Tang *et al.* *Id.* at p. 5. With reference to claims 14, 17, 21 and 24 that depend either directly or indirectly from independent claim 1, the Examiner states that Hunter *et al.* teaches silicone stents with coatings of radioactive materials and that Tang *et al.* teaches use of Barium salts as a therapeutic salt. *Id.* at pp. 4-5. However, neither Hunter *et al.* nor Tang *et al.* makes up for the deficiency in the Sahatjian and Miller *et al.* combination, as neither of the references teaches or suggests a porous material loaded with particles of a water-insoluble salt of a therapeutic material as recited in claim 1. As such, claims 14, 17, 21 and 24 that depend either directly or indirectly from and add further features to independent claim 1 are patentable over the afore-mentioned combinations of references for that reason alone.

In view of the above arguments, Appellant requests that the rejection of claims 1, 2, 4, 5, 9, 10 and 13-24 under 35 U.S.C. §103(a) be reversed.

Respectfully submitted,

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